

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
24 October 2002 (24.10.2002)

PCT

(10) International Publication Number
WO 02/083012 A1

(51) International Patent Classification⁷: **A61B 17/32**

(21) International Application Number: PCT/TR01/00015

(22) International Filing Date: 11 April 2001 (11.04.2001)

(25) Filing Language: English

(26) Publication Language: English

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HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

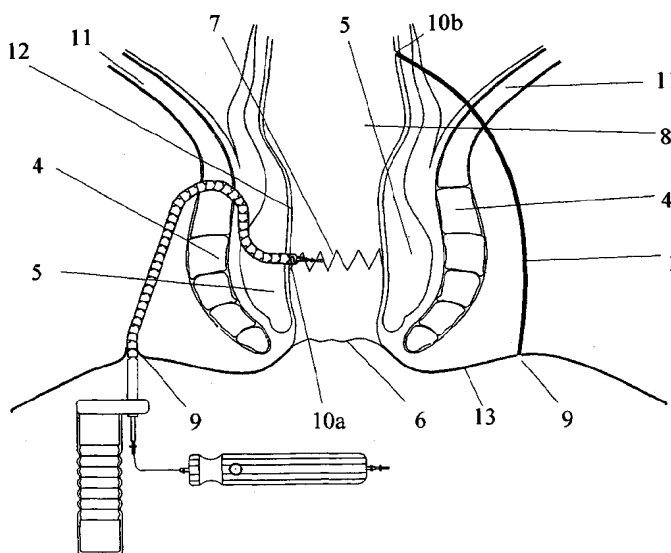
Published:

— with international search report

(81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR,

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(54) Title: DEVICE FOR EXCISION OF A FISTULA



(57) Abstract: A combined system aiming at the treatment of anal fistula has been developed. Fistulotomy set contains, a vibrating guide facilitating localisation and cannulation of the fistula tract and a fistulotomy which is an electromotor-driven instrument transferring 3 D axial movement by means of spherical joints threaded along the central spiral guide to the blade at the tip. We believe that this set will provide significant advantages in the treatment of anal fistulas namely shortening the hospital stay and convalescence period, reducing the cost of the treatment, minimizing the postoperative morbidity and more importantly, prevention of inadvertant anal incontinence.



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DESCRIPTION

DEVICE FOR EXCISION OF A FISTULA

The present invention pertains to a surgical instrument for excising and removing a fistulous tract from the canal, and in particular, for treating anal fistulae by performing a minimally invasive operation in an efficient
5 manner and within a short time.

FIELD OF INVENTION

Since the anatomic and physiological structure of the anal tract have very specific characteristics, treatment of the fistulae which have occurred there is difficult in a number of terms.

10 Since incision of the external sphincter and the lavatory muscle will cause anal incontinence, treatment requires to preserve the integrity of said muscles.

Anal fistulae can be divided into two categories: simple (which can be treated with fistulectomy) and complicated (where fistulectomy is
15 contraindication).

Simple fistulae can be easily treated by performing fistulectomy and then letting the secondary healing. Treatment methods employed for treating complicated fistulae include application of seton or performing periodic surgical operations to incise the fistulous tract. Said methods take a long
20 time, cause many difficulties for the patient, and most of the time, turn out to be unsuccessful.

Treatment of a fistula requires to open the bleeding tissue to the fistulous

tract for the purpose of removing dead tissues from the fistulous tract, removing the secreting mucosa, and moving the granulation tissue to fill
25 the tract.

The foregoing objects can be achieved by performing fistulectomy on a simple fistula, but fistulectomy is not performed on complicated fistulae, otherwise it will cause anal insufficiency. Therefore, the seton method is employed for incising the muscle tissue in stages within a long time and
30 for letting it heal. Seton is applied for the expectation that the granulation will develop thanks to the excite starting when the living tissue is incised and then will fill the fistulous tract. This method is not necessarily successful for al cases, and can lead to a particular loss of continence. Therefore, the present device is significantly needed to treat such kind of
35 fistulae.

The present device incises the dead tissues and fibrous structures having developed secretory epithelium from the fistulous tract, and removes them from the environment. Thus, the edge of the fistulous tract is equipped with viable tissues which activate the excited granulation, so
40 that the granulation starting there fills the fistulous tract and ensures treatment of it.

COMPARISON WITH A DEVICE FOR THE SAME OBJECT

Review of the relevant literature revealed a device designed for treatment of fistulae, patent number US05643305. The device in
45 question is based on the principle of incising and removing a simple fistula together with living tissue outside the fistulous tract, and moves along a single dimension. Its operating system is unable to meet the needs in terms of its function and fistulae treatment. Furthermore, neither its operating system nor its shape bears any similarity to the present

50 invention.

BRIEF DESCRIPTION OF THE INVENTION

The present invention is an instrument capable of overcoming all kind of problems associated with treatment of fistulae. It can be easily used for all perianal fistulae. It turns a risky operation into a simple one especially
5 for complicated fistulae, and ensures them to heal in a short time.

An operation made by using the present invention will both protect the anatomic and physiological characteristics of the perianal tract, and meet the surgical principles needed for treatment of fistulae.

The present invention is a device generating an axial circular rotational
10 movement through an electric motor, conveying said movement by means of a spherical shaft or a tubular shaft to its incision end in a manner fully controlled in three dimensions, as directed by its guide, and ensuring the cutting end to incise for the purpose.

The present invention is a fistulectomy set consisting of cannulation
15 guides, fixing guides, a cutting end, a spherical or tubular shaft , a movement control and stabilization part, a movement conveying element, and a handle (motor housing).

BRIEF DESCRIPTION OF THE DRAWINGS

**Fig.1: Fistulectomy performed on an extra-sphincteric fistula and
20 view of an supra-sphincteric fistula.**

Anal fistulae generally begins on the crypts above the dentate line (7), passes through the tissue and ends on the perineum skin (9). Sometimes an inner opening can form on the upper sections of the rectum (10b) or on the sigmoid colon (10c), The more the fistula's opening in the
25 perineum (13) moves away from the anus (6) , the more the fistulous tract gets complicated. No fistulectomy can be performed on fistulae whose tract passes outside the internal sphincter (4) and external sphincter (5). The present invention contains a shaft system (36,39) enabling it to proceed along such complicated fistula tract.

30 **Fig.2: Fistulectomy performed on an supra-sphincteric fistula and view of an extra-sphincteric fistula.**

Supra-sphincteric fistula begins on the perineum (13) at a point far from the anus (6), pierces through the pubo-rectal muscle (11) and ends on the upper section (10b) of the rectum. It cannot be treated with fistulectomy,
35 because the latter will damage the pubo-rectal muscle (11) and give way to incontinence. It is apparent that the present invention is able to incise said fistula in a simple way (10b), from the perineum (9) to the internal opening.

**Fig.3: View of cannulation of the tract by means of the cannula
40 guide (15), beginning on the external opening of the perineum (6) and proceeding up to the internal opening (10) of the rectum (8).**

Fig.4: Schematic views of fistülectomy performateral an extra-sphincteric fistula with pelvic inflamational (4a) and the said fistül(4b).

45 This figure shows how the present invention is used along a hard guide on an extra-sphincteric fistula causing pelvic inflammation It also shows how the present invention incises a fistula from the fistula opening (9) located in the perineum (13) up to the internal fistula opening (10c) located in the sigmoid colon along a hard guide (29).

50 **Fig.5: View of the movement of the spherical shaft (36) on the wire (25) and spring (26) guides.**

The end of the wire guide (25) is fixed to the guide end holding apparatus (51) inside the rectum (8). The wire guide (25) stabilizes the spring guide (26). The spherical shaft (36) uses the spring guide as a
55 directing rail while it operates.

Fig. 6: View and details of the cannula guide system.

View of an embodiment of the present invention designed to facilitate pinpointing a fistula and cannulating the fistula along its soft tissue, run by an electric motor (housed inside the handle (14), containing a
60 directing part (16, 17) at the end of the cannule guide designed for either eccentric rotation (6T) or vibrational movement (6V).

Fig. 7: View of general use of the present inven'tion.

View of the relation between the accessories: the wire guide (25), the spring guide (26), the incision ends (31, 32), the spherical shaft or
65 tubular shaft (36, 39), the intermediate part (42) controlling and moving

the spherical or tubular shaft, the movement sliding apparatus (41) ensuring the spring guide to work far from the device's body, the handle (53) directing the device in this combination, the intermediate part (49) enabling the operator to place the spring guide on the wire guide inside
70 the fistula, the tensioning and fixing handle (46) that tensions and locks the spring guide.

Fig. 8: View of movement control guides and incision ends.

General view of the wire guide (25) and spring guide (26) or the hard guide (29) ensuring the present invention to be used by the operator in a
75 safe and controlled manner depending on the type of the fistula, and the spring guide's stopper (28). View of various incision ends (31,32,33,34,35) providing various functions and meeting various demands depending on the type of the fistulous tract.

Fig.9: View of the spherical shaft and its details.

80 View of the spherical shaft and its sfctional details(36) rotated by a part located behind it, the special circular protrusions (37) conveying said rotation to next part, the longitudinal canals (38) receiving the rotation conveyed by said protrusions, the central canal (40) serving as a bed for the wire guide (26), and the body.

85 **Fig.10:** View of the spherical shaft (36), tubular shaft (39) and spring guide (26) which are the moving parts of the present invention, and its functional movements.

Fig.11: View of the movement sliding part. In order to enable the present invention to move forward and backward along the wire guide, this intermediate part (43) slides the axial rotation in parallel with its direction. Said intermediate part consists of a part (42) controlling the spherical shaft, a gear (44) ensuring said part to rotate axially, a wheel (45) conveying the axial rotation provided by the electric motor, and a body ensuring said gear and wheel to work in harmony with each other and housing them. See Fig.10 for the view and side view of the relation of said parts with each other.

Fig.12: View of the details of the guide end holding apparatus, and of the guide tensioning and fixing handle.

The guide end holding apparatus (51) catches the drop-shaped (27a) or spherical (27b) end of the wire guide thanks to the holding bed (52) located in the center of the holding cap. The guide tensioning and fixing handle (46) ensures the operator to place the spring guide (26) on the wire guide (25). It also stabilizes the spring guide after the latter is placed on the wire guide.

105 HOW TO USE THE DEVICE

Radiological examination is conducted on the patient by means of fistulography in order to delineate the shape and direction of the fistula.

The operator inserts the vibrational cannulation guide or rotational cannulation guide into the fistula's opening in the perineum, and reaches to the other opening of it inside the rectum.

Thus the fistula is mechanically pinpointed. Then the operator takes the

cannulation guide out of the fistula. The operator uses the wire guide to push the fistula forward from its opening in the perineum, along the tract, into the anal canal. Then the operator pushes the fistula along the
115 spring guide up to its end. The ends of both guides are held and fixed with the holding apparatus inserted into the anal canal. The spherical articulated shaft having an incision end is attached on the controlling and fixing part attached to the movements sliding part attached to the holding handle.

120 The operator passes the spring guide through the special channel located in the center of the intermediate part carrying the moving spherical articulation group attached to the holding handle, and pushes it out of said channel. Finally, the operator attaches the spring guide to the tensioning handle.

125 There is a blade unit on the spring guide, attached to the moving spherical articulation, so that the operator switches the motor on and pushes said blade unit into the fistulous tract. Then the operator incises the fistulous tract up to the main channel to remove it.

CLAIMS

1. A system conveying the axial rotational movement along a central guide in three dimensions and in a fully controlled manner consists of a vibrating cannulation guide helping to find the fistulous tract, which
5 might have a rotational head; a wire and spiral guide acting as a spring and controlling the spherical shaft in the cannulated fistula; a hard guide directing the spherical shaft's rotation in sinus-shaped fistulae; cutting edges mounted on the activation shaft and used for cutting inside the tract; activation shafts mounted on the sliding part; a control and
10 mounting part fixing the spherical shaft and transferring the axial rotational movement to the spherical articulated shaft; a sliding part transferring the rotational movement given by the electric motor to the mounting part; a handle also acting as a housing for the motor; a guide end holding apparatus fixing the ends of the guides inside the rectum;
15 and a fixing handle stretching and fixing the spiral guide on the spring guide.

2. As described in claim(1), Cannulation Guide is a guide facilitating to pinpoint a fistula (1,2), ensuring the fistula
to be cannulated along its soft tissue, powered by an electric motor (14),
20 having a directing part (16,17) on its end proceeding with vibration (23) or eccentric rotation (20).

3. As described in claim(1) Wire Guide is a wire used for cannulating the fistula, carrying and fixing the spring guide (26), having a drop-shaped end (27a) or a spherical end (27b), made of metal or plastic.

25 4. As described in claim(1) Spring Guide is a part placed inside the
fistula cannulated by the wire guide (25) but outside the wire guide,
having an incision end (31,34) movable in three dimensions in a fully
controlled manner, being in certain dimensions, having a stopper (28) on
both of its starting and ending sections, made of a hard metal wire coiled
30 in the form of a spring.

5. As described in claim(1) Hard Guide is a guide (29) made of a hard
metal wire wrapped with a thinner wire. It has a drop-shaped metal end
on its starting section. It serves as a rail for the spherical shaft (36) or the
tubular shaft (39) to treat a fistula whose internal opening does not open
35 to the rectum.

6. As described in claim(1) Incision Ends is an apparatus (31,24) which
contains spiral flat incision ends (32) or circular incision ends (35)
attached on a metal pipe (30) containing grooves (38) matching the
movement conveying protrusions (37) of the spherical shaft (36).

40 7. As described in claim(1) Spherical Articulated Shaft shaft consists of
a number of units conveying the axial rotational movement coming from
the holding unit (42) to next part. Said units are located on a relative
plain standing at a right angle to the horizontal axis of the spherical
part's center. It also consists of special circular-sectioned protrusions
45 (37) standing vertical to each other, and a number of longitudinal
grooves (38) receiving the rotational movement conveyed by said
protrusions. It can be bent at any direction without problem.

8. As described in claim(1) Tube Carrying Axial Rotational Movement is an apparatus (39) receiving the rotational axial movement from the
50 controlling and fixing part (42) , conveying it to the incision ends in a fully controlled manner, having longitudinal slits sanding at a right angle, made of hard but flexible plastic or metal, moving along a central spinal, in tubular shape.

9. As described in claim(1) Articulation Controlling Part is an
55 intermediate part (42) connecting the spherical articulated shaft to the handle, receiving the axial rotational movement from the electric motor and conveying it to the spherical articulated shaft or to the pipe carrying said movement, and, in turn, to the incision end.

10. As described in claim(1) Movement sliding part is an intermediate
60 part designed for allowing the operator to use the axial rotational movement taken from the electric motor at his discretion, for facilitating to apply the wire guide's and spring guide's movements independently to the fistula, and for sliding the application axis on a plane parallel with the axis of holding handle.

65 11. As described in claim(1) Holding Handle (Motor Housing)is a special handle (53) housing both the electric motor and the gears.

12. As described in claim(1) Guide End Holding Apparatus is an apparatus (51) preventing the spring guide (25) and the spring guide (26) from moving independent from each other inside the internal opening
70 (10) of the fistula.

13. As described in claim(1) Guide Tensioning and Fixing Handle is a handle fixing the spring guide (26) on the wire guide. It consists of two parts, and contains a holding section having a wire guide groove (50) in it, a tip (47) pushing the spring guide along the spring guide, and a clip (48) fixing the wire guide in the holding section.

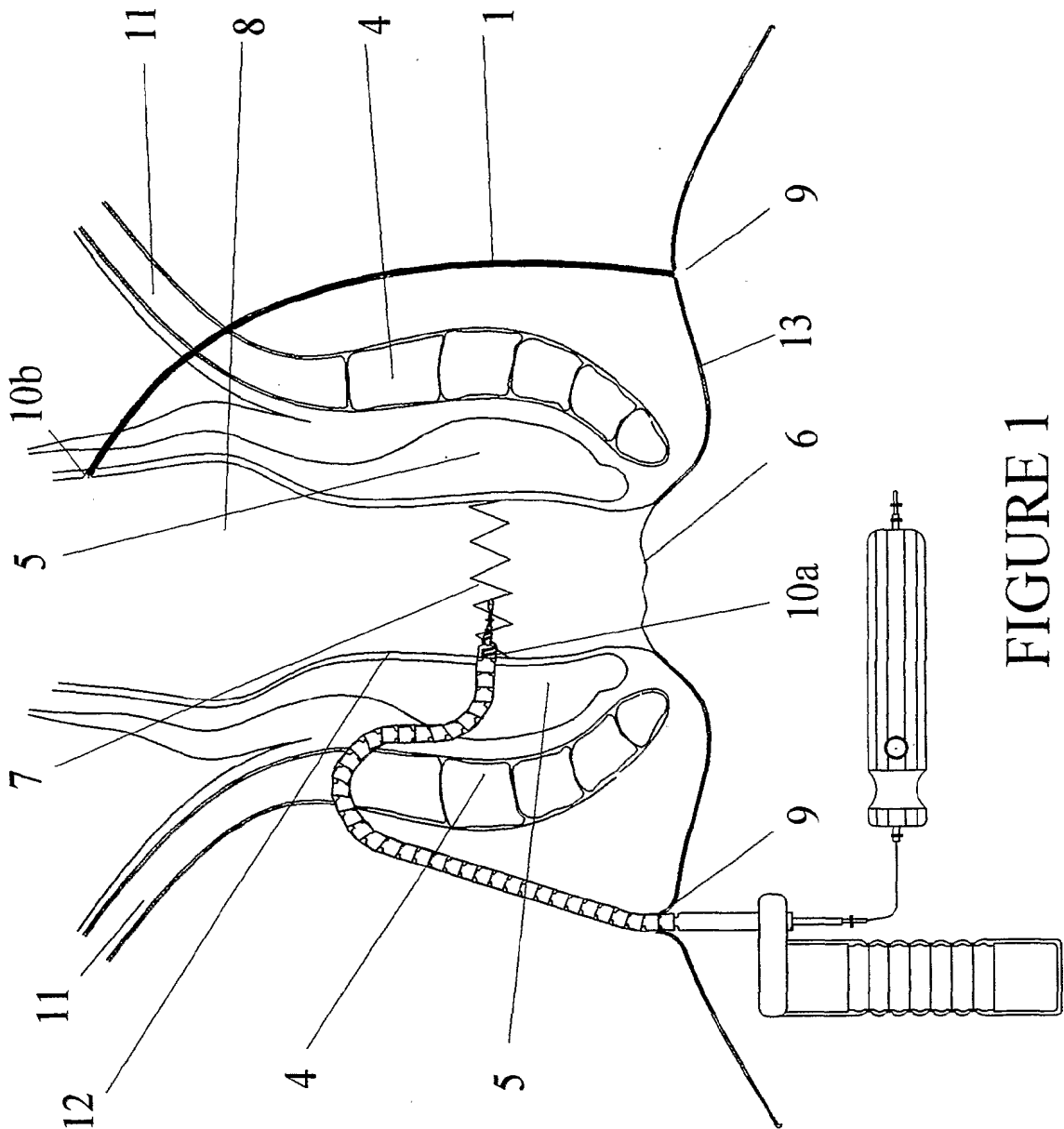


FIGURE 1

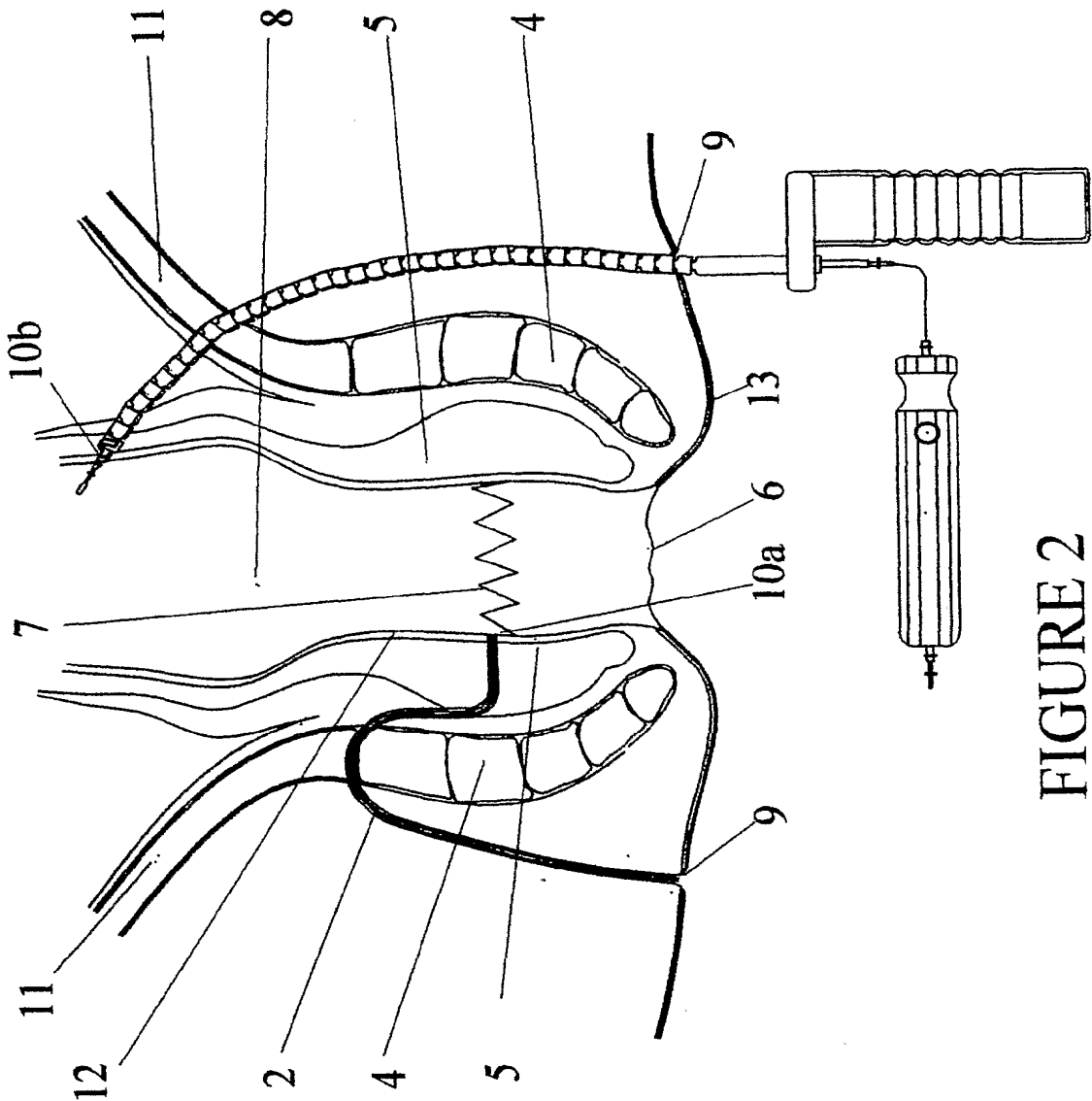


FIGURE 2

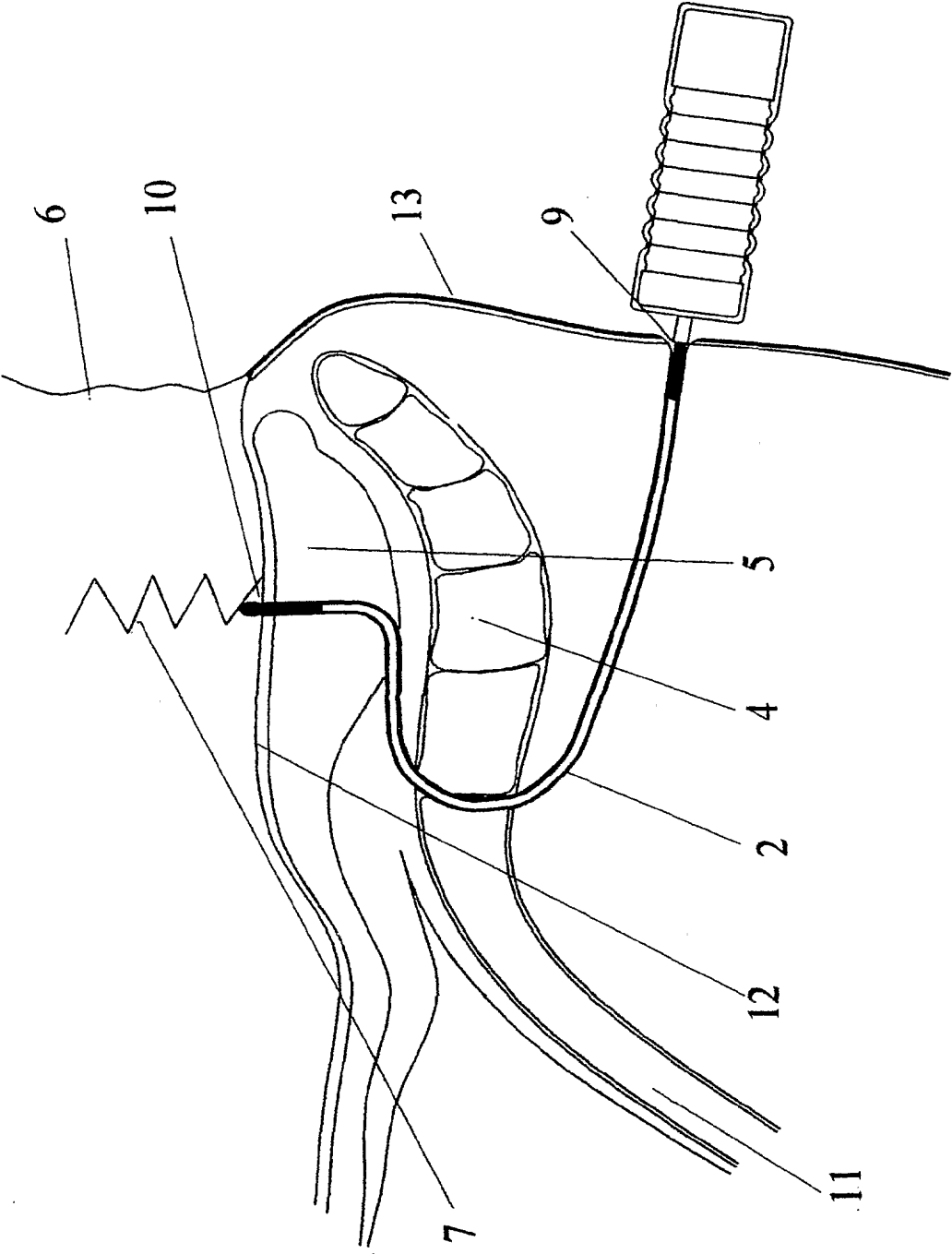


FIGURE 3

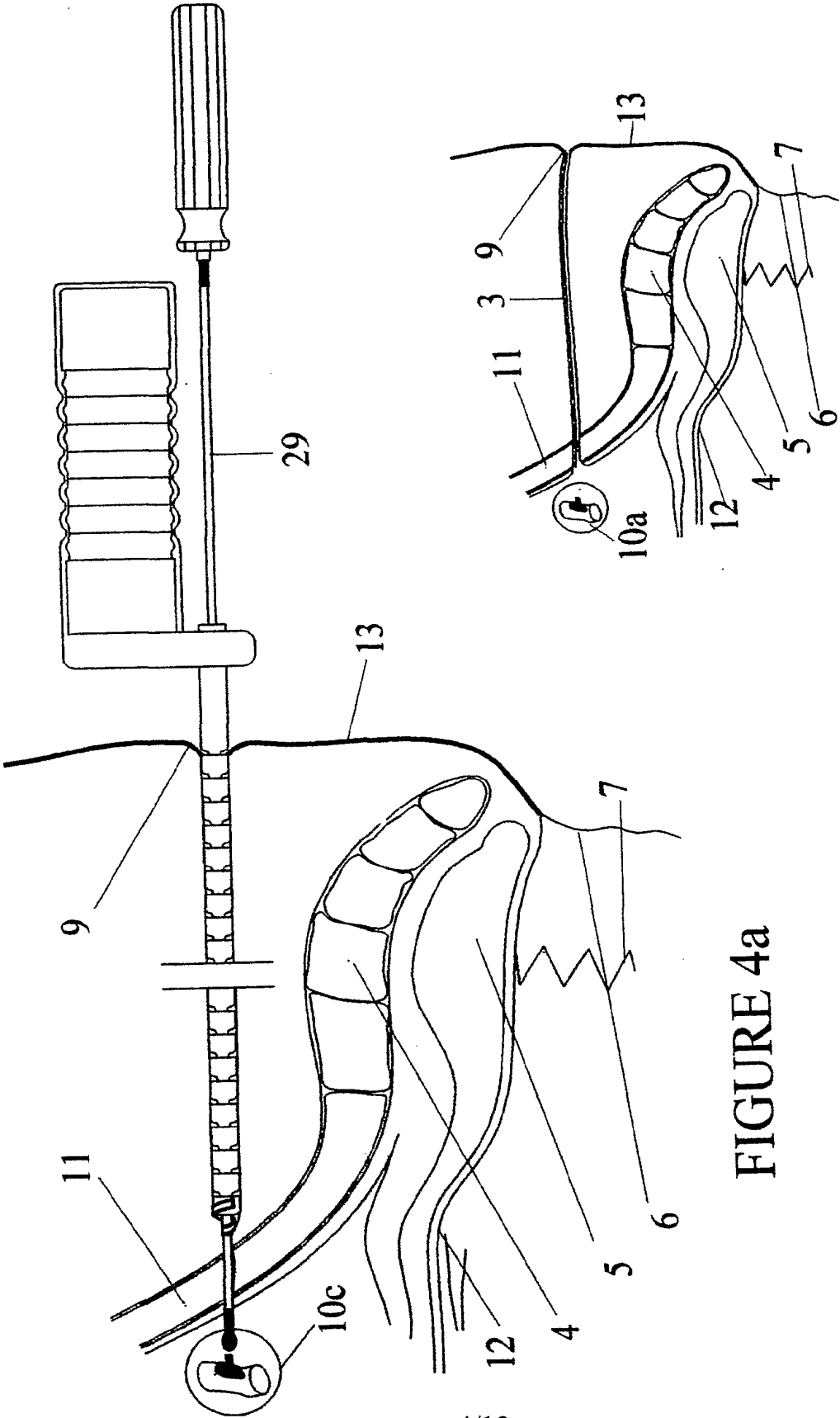


FIGURE 4a

FIGURE 4b

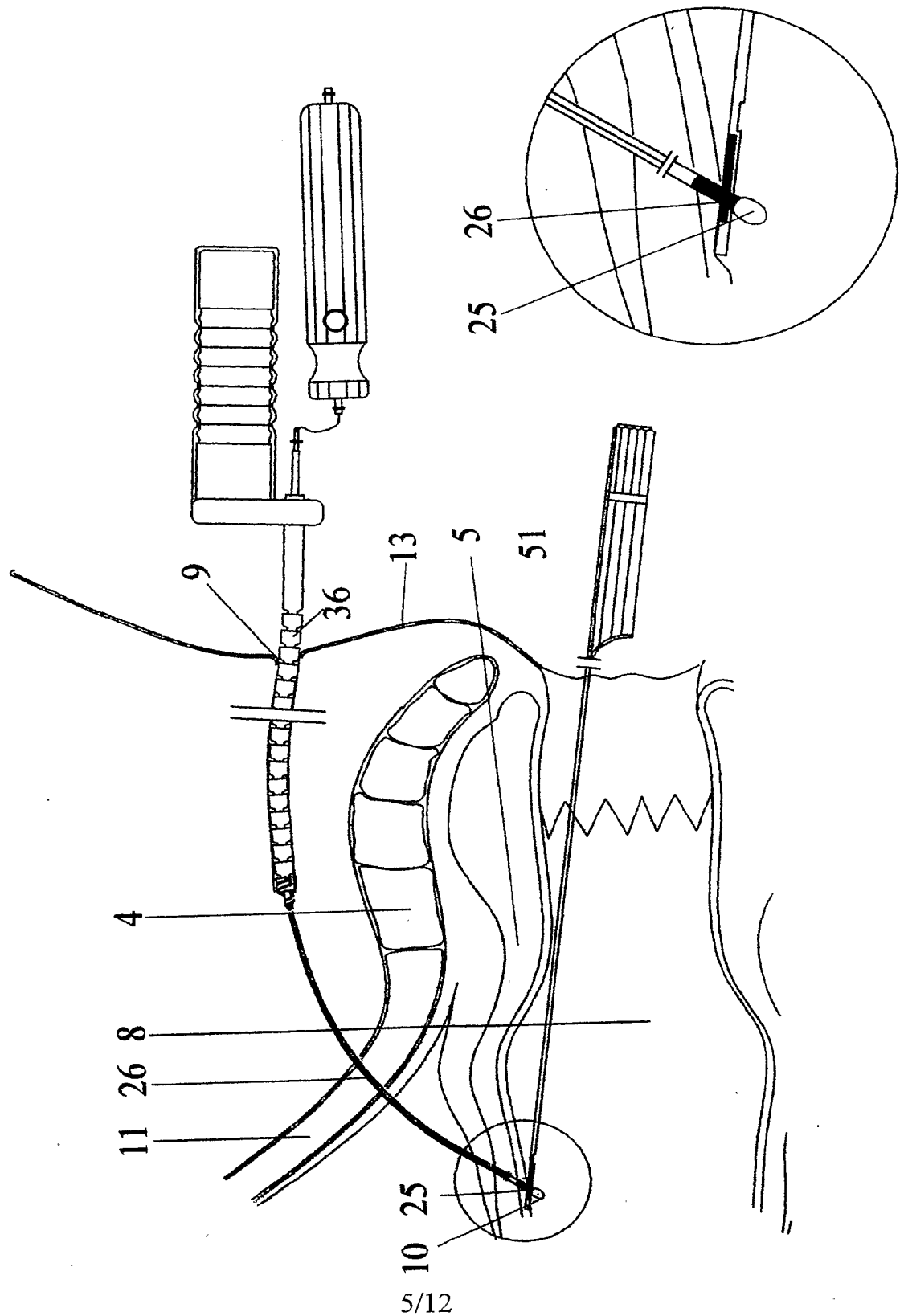


FIGURE 5

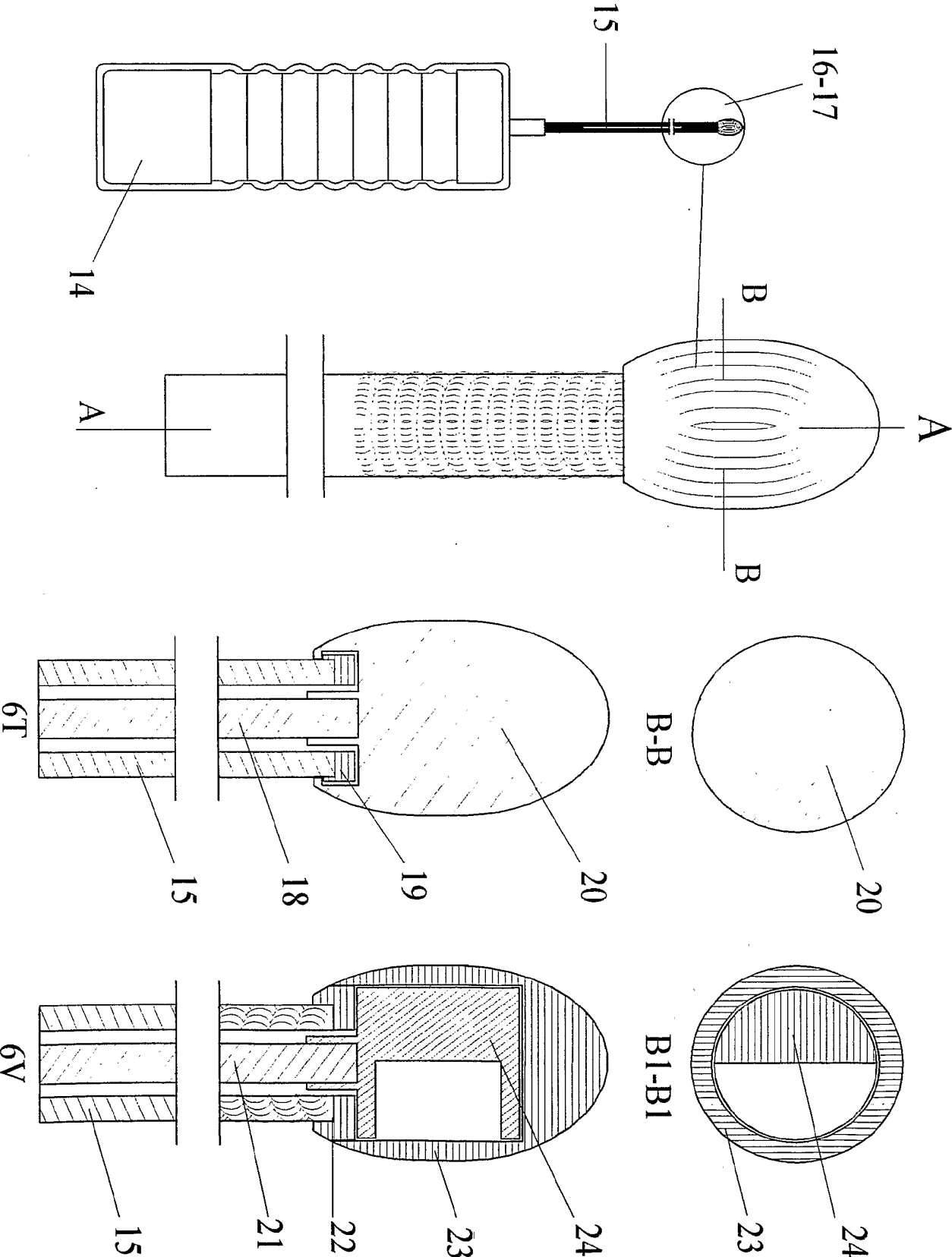


FIGURE 6

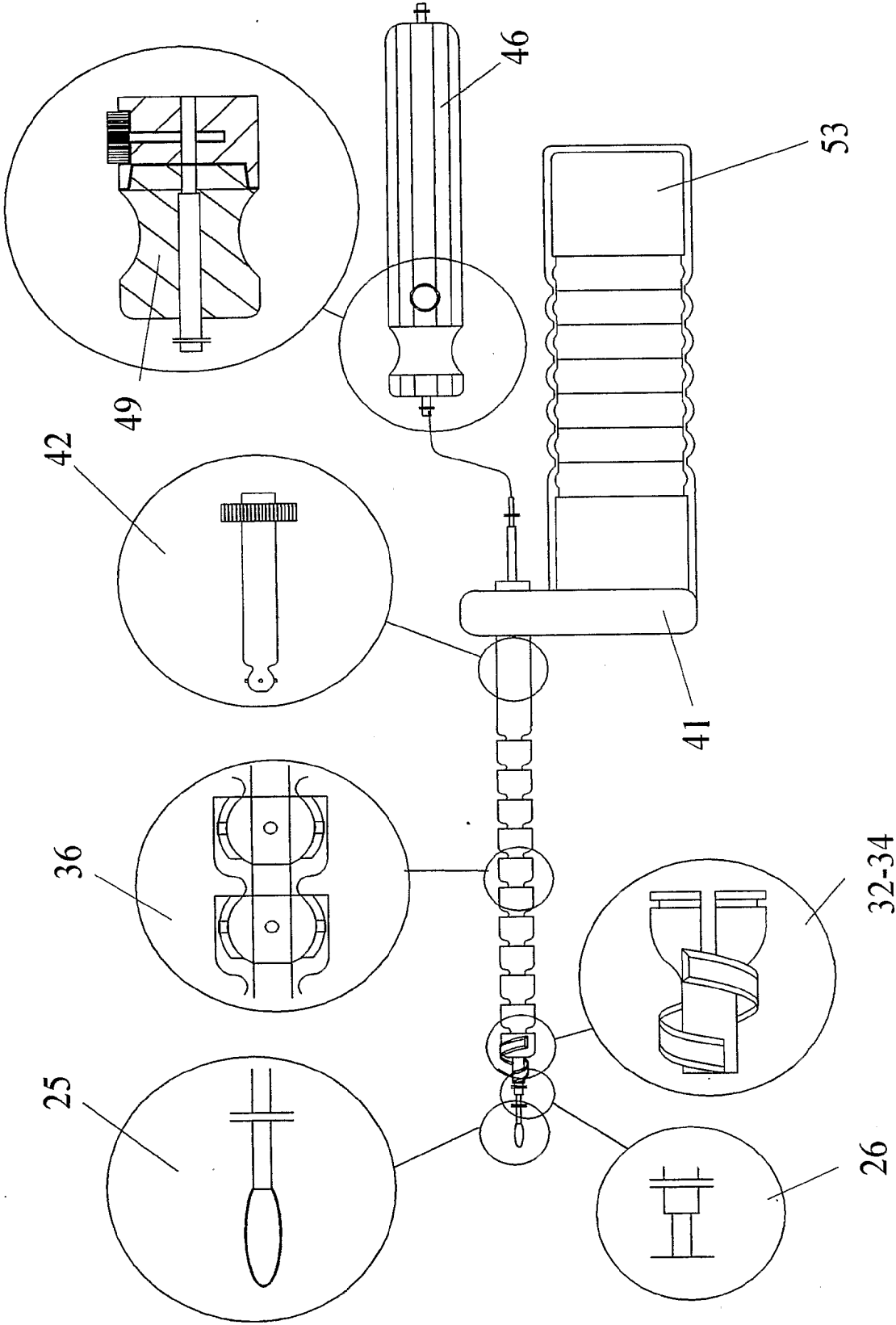


FIGURE 7

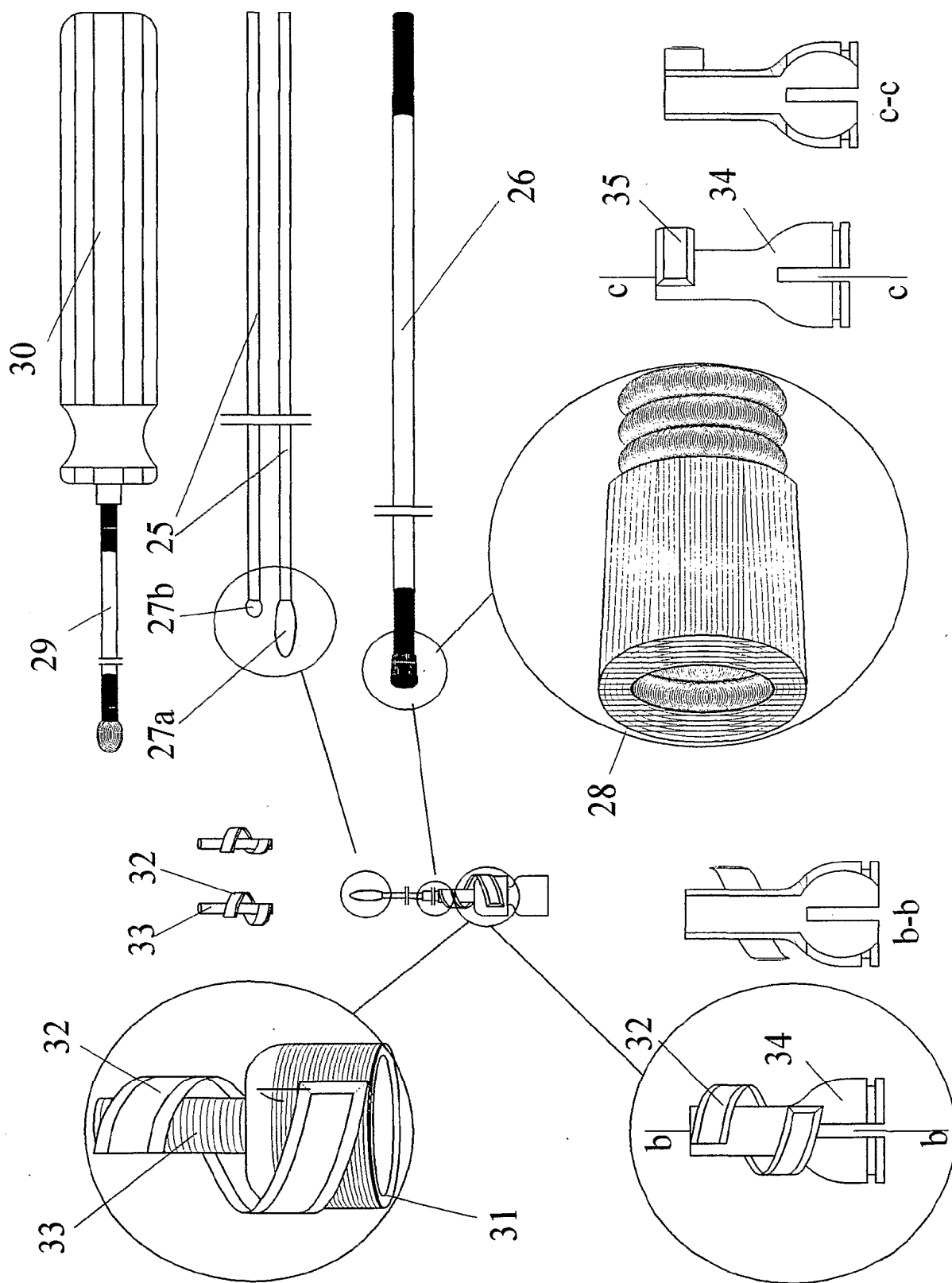


FIGURE 8

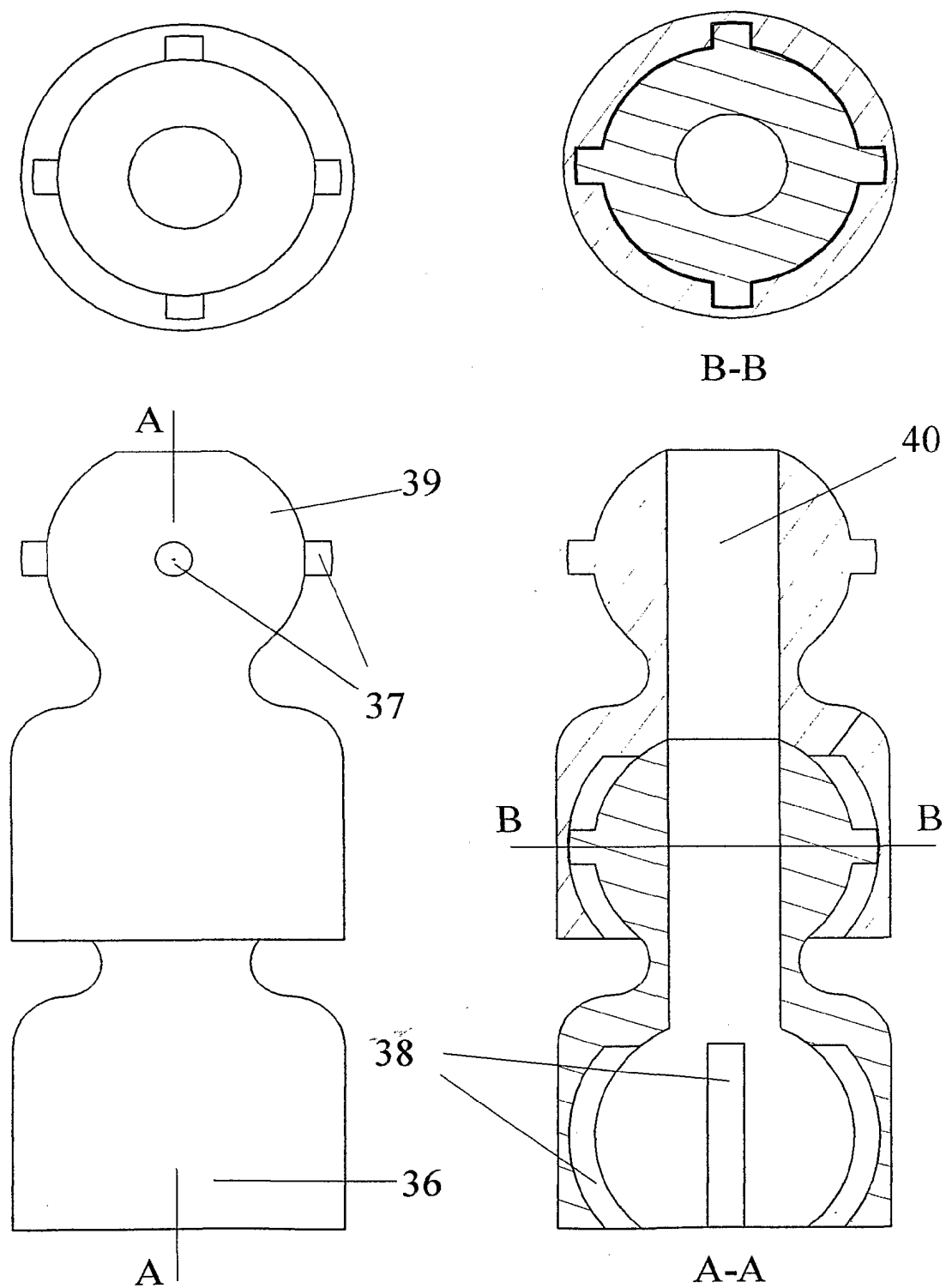


FIGURE 9

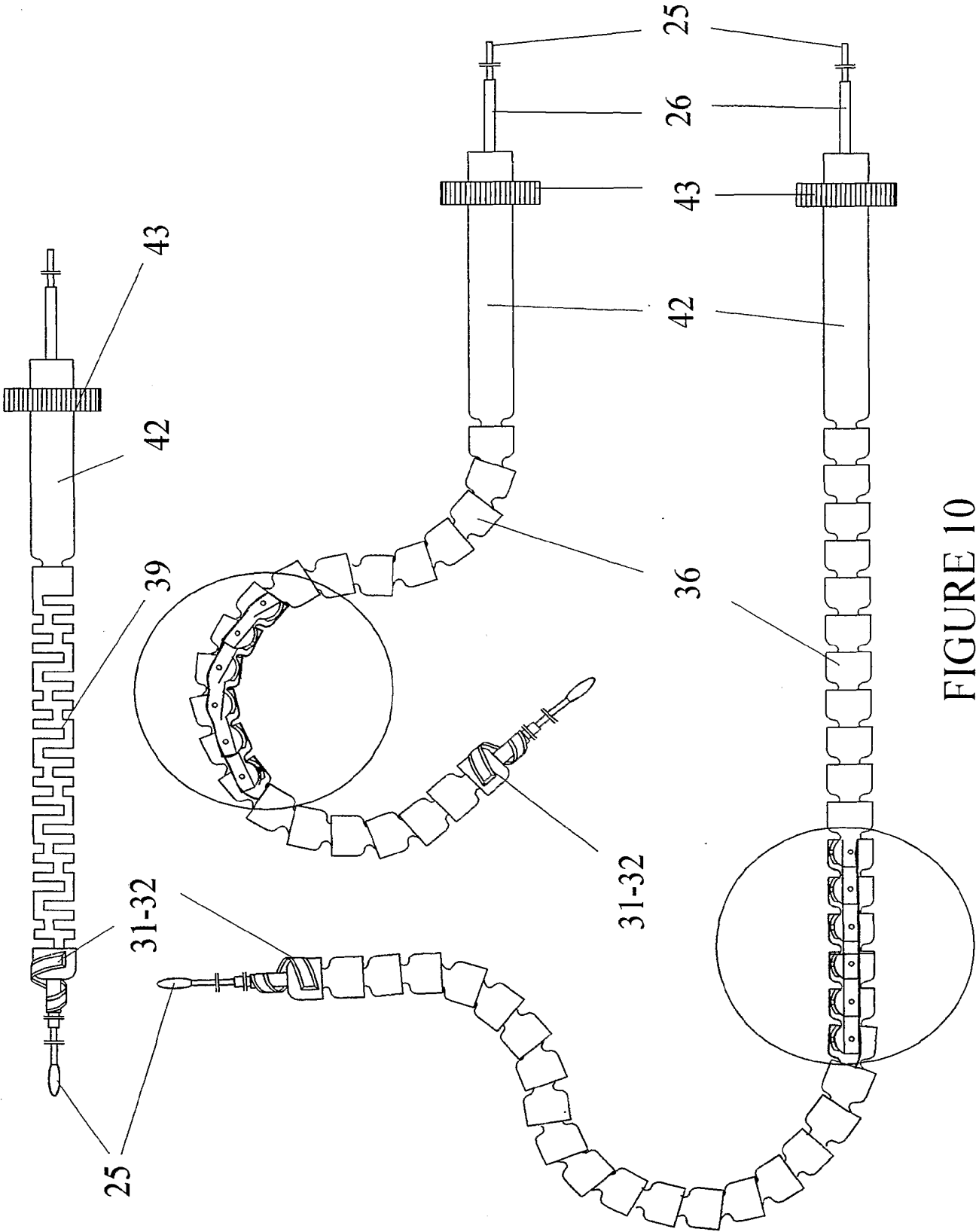


FIGURE 10

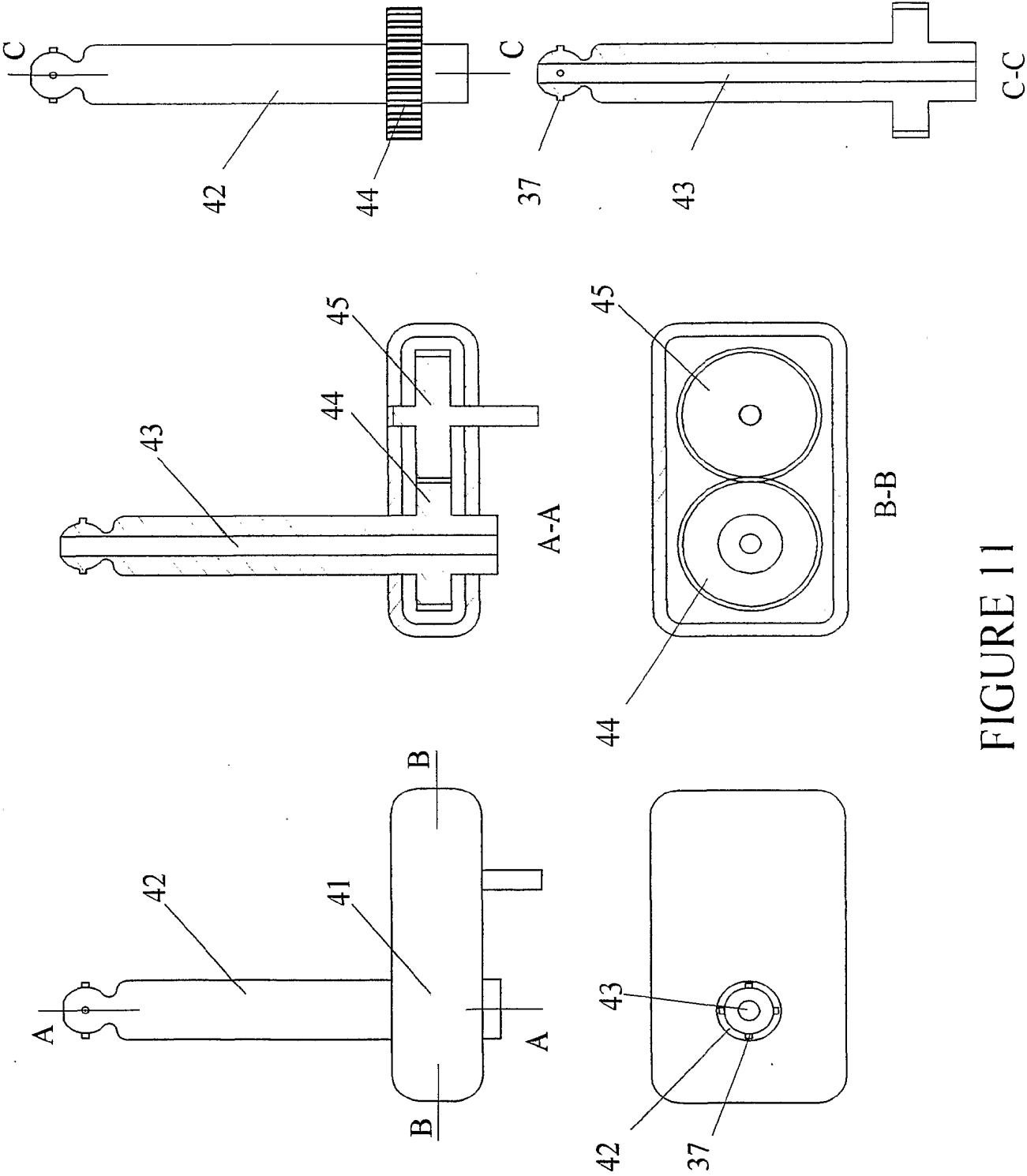


FIGURE 11

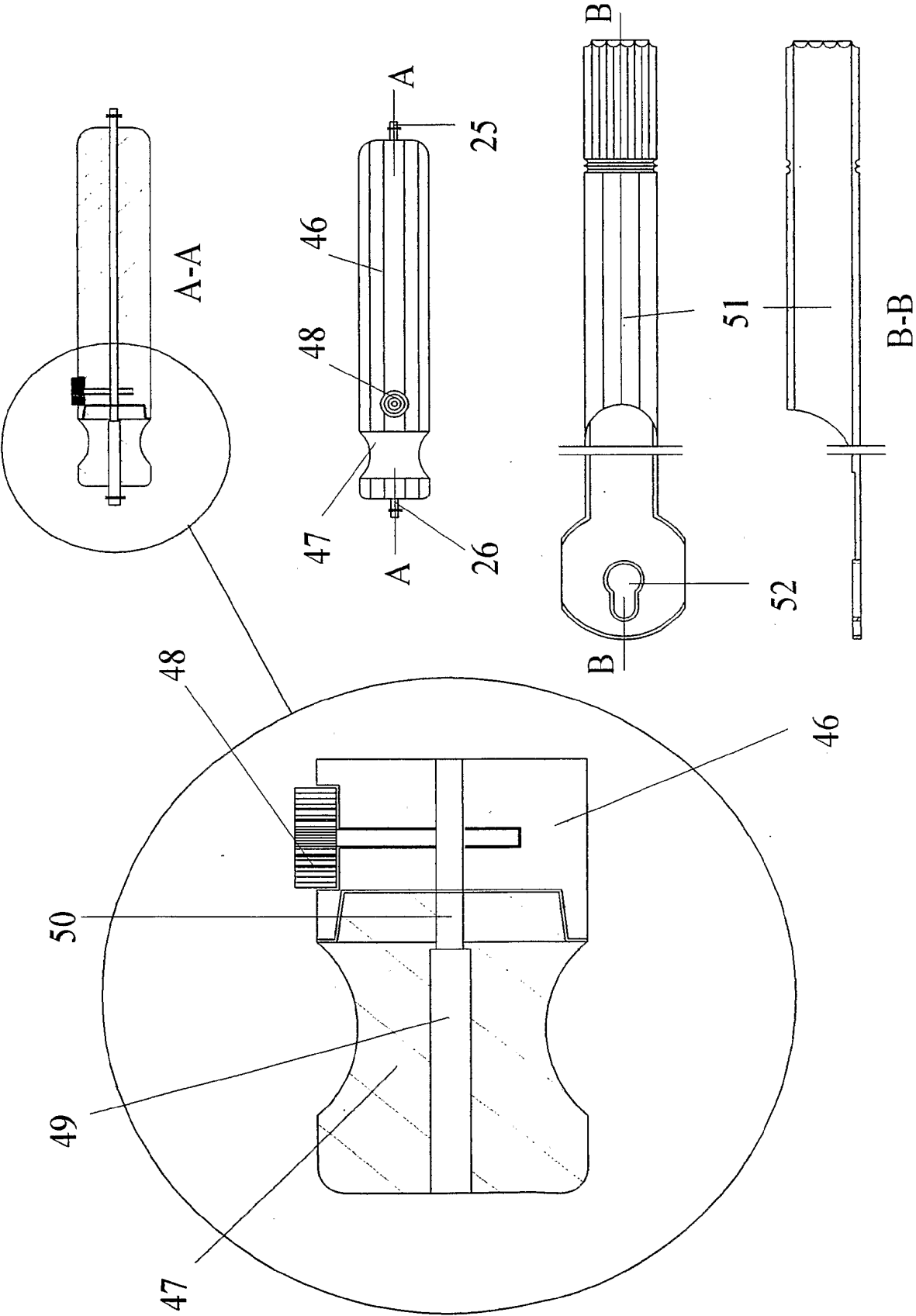


FIGURE 12

INTERNATIONAL SEARCH REPORT

International Application No
PCT/TR 01/00015

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/32

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

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10 December 2001

Date of mailing of the international search report

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Name and mailing address of the ISA

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